Patient Information Sheet

An investigation of the feasibility, reliability and acceptability of using of ultrasound to assess muscle echogenicity and size in key speech and swallowing tissues before and after radiotherapy in a head and neck cancer population.

Introduction
We would like to invite you to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Part 1: Tells you the purpose of this study and what will happen to you if you take part.
Part 2: Gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

Thank you for reading this.

What is the purpose of the study?

Radiotherapy is often used to treat head and neck cancer. Common side effects of the radiotherapy are changes to the muscles of swallowing and speech that lead to difficulties eating, drinking and talking. Speech and Language Therapists work with patients to assess and treat these difficulties, but at the moment we do not have a detailed understanding of what happens to size and structure of the muscles because of radiotherapy. Ultrasound is technique that could help us to understand changes in the muscles in more detail, and potentially guide swallowing and speech rehabilitation. This study is to find out whether using ultrasound is feasible for patients undergoing radiotherapy for head and neck cancer, and whether patients find it an acceptable assessment tool. We will also use the ultrasound assessment findings to describe differences in muscles before and after radiotherapy.

Why have I been chosen?

We have asked you to take part because you have been diagnosed with head and neck cancer and will be treated with radiotherapy at Imperial College Healthcare NHS Trust (ICHT).

Do I have to take part?

It is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

If you would like to take part we would like to have your details so that we can contact you for further discussion – you can choose how we contact you for example by telephone or email. We will then contact you after 24-48 hours to discuss any questions you have about the study and if you would like to participate. You will also be given longer to decide if you need it, up until you start treatment. You will be asked to sign a consent form before we start the research.

If during the study you change your mind about participating, or are no longer able to consent to the study you would be withdrawn from the study. This would not affect your clinical care at all and no further data would be collected from you, however data collected from the period when consent was given would still be used in the study.

What will happen to me if I take part?
At your next clinical appointment at a time that suits you, you will be asked to sign a consent form. We will then ask you to fill in two questionnaires – an MD Anderson Dysphagia Index (MDADI) and a Speech Handicap Index (SHI). These will take no more than fifteen minutes to complete.

We will also complete an ultrasound assessment of the muscles of your face, tongue, and neck. This will involve applying gel to an ultrasound probe and using this to take images and videos of the muscles. This will be recorded and stored on an NHS computer using password protection and encryption. They will be saved as part of your electronic patient record as per usual clinical care protocols. This assessment will take approximately 30 minutes.

We will then repeat the questionnaires and ultrasound assessment once you have finished your radiotherapy treatment. We will aim for this to take place on the same day as a follow up clinic appointment or scan, between 6 weeks and three months after treatment finishes. These assessments will all take place at Charing Cross Hospital, ICHT.

We will also ask you to fill in a short survey to ask you about the experience of having the ultrasound assessment. This can be completed electronically or on paper according to your preference and at any time you would prefer.

You should expect to be part of the research study for no more than 6 months.

What are the possible disadvantages and risks of taking part?
There are no risks to taking part. The main disadvantage relates to the time taken for the assessments, but this will be lessened by trying to match these with times you have to be at the hospital for clinical appointments anyway.

What are the possible benefits of taking part?
We cannot promise the study will help you but the information we get might improve the treatment of people with head and neck cancer in future.

What if new information becomes available?
Sometimes during a research project, new information becomes available about the assessment that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, this will not affect your clinical care. If you decide to continue in the study, you will be asked to sign an updated consent form.

What happens when the research study stops?
Once the research study finishes you will remain under the care of the ICHT Head and Neck Cancer Multidisciplinary team for your ongoing clinical care.

What if something goes wrong?

Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS resolution for NHS Trusts in England, which apply to this study. This does not affect your legal rights to seek compensation.
If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator Dr Gemma Clunie gemmaclunie@nhs.net

The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Research Governance and Integrity Team.

HOW WILL WE USE INFORMATION ABOUT YOU?

Imperial College Healthcare NHS Trust is the sponsor for this study and will act as the Data Controller for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College Healthcare NHS Trust will keep your personal data for:

• 5 years after the study has finished in relation to data subject consent forms.
• 5 years after the study has completed in relation to primary research data.

The study is expected to finish in October 2025

For more information / confirmation regarding the end date please contact the study team, see 'WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED' for contact information.

We will need to use information from you and from your medical records for this research project.
This information will include your:

- Initials
- Name
- Contact details

People within the Trust and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact details) is accurate.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.
As an NHS Trust we use personally-identifiable information to conduct research to improve health care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

Imperial College Healthcare NHS Trust - “performance of a task carried out in the public interest”; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College Healthcare NHS Trust) rely on “scientific or historical research purposes or statistical purposes

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College Healthcare NHS Trust will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College Healthcare NHS Trust will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

• Other Imperial College Healthcare NHS Trust employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College Healthcare NHS Trust agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third-party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

The following Research Collaborators / Partners in the study: Some pseudonymised data will be collected via Imperial College London Qualtrics software or will be shared for analysis purposes with Imperial College London.

POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College Healthcare NHS Trust and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

COMMERCIALISATION

Data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample / data analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have because some research using your data may have already taken place and this cannot be undone.

- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to gemmaclunie@nhs.net, or
- by ringing us on 020 33111492.

COMPLAINT

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to gemmaclunie@nhs.net, or by ringing us on 020 33111492.

Following our response, if you are not satisfied please contact Imperial College Healthcare NHS Trust's Data Protection Officer via email at imperial.dpo@nhs.net via telephone on 020331304001 or via post at 8th Floor of Salton House, ICT Division, St Mary's Hospital, Praed Street, London, W2 1NY

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

What will happen to the results of the research study?

A final study report will be produced summarising the information we have learned. This will be anonymous. Quotations from the survey you fill in may be used in this report, but these will be anonymous. The report will be sent out to patient charities, forums and social media and published on the Imperial College website. If you would like a copy of the report, we will be able to send it to you. The results will also be used to improve the Speech and Language Therapy care pathway for patients with head and neck cancer at Imperial College Healthcare NHS Trust. The results will also be used to guide further research projects into the use of ultrasound in head and neck cancer.

Who is organising and funding the research?

This study is funded by a National Institute of Health and Care Research (NIHR) Senior Clinical and Practitioner Research Award Fellowship (NIHR 304447) and a Seed Fund Grant from the Department of Surgery & Cancer, Imperial College London.

Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by xxxx REC.

Contact for Further Information

Please contact Dr Gemma Clunie on the following contact details:

Name: Dr Gemma Clunie
Telephone: 020 33111492
Email (if applicable): gemmaclunie@nhs.net

This copy of the participant information sheet is for you to keep, and if you consent to take part you will also be given a copy of the signed informed consent form. Thank you for reading this information sheet and for taking part if you choose to.